UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,433	04/15/2005	Takeshi Ito	KUZ-0024	8651

7590 10/15/2008

Jane Massey Licata or Kathleen A Tyrrell
Licata & Tyrrell
66 East Main Street
Marlton, NJ 08053

EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
10/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,433	ITO ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/2/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 7/2/08

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 7/2/08 was filed after the mailing date of the Specification on 4/15/05. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Hori et al (USPN 5,814,032 hereafter '032). The claims are drawn to a transdermal patch formulation comprising a polyisobutylene mixture, a mineral oil and fentanyl.

The '032 patent discloses a pressure sensitive adhesive formulation comprising a mixture of high and low molecular weight (polyisobutylene in a ratio of 1:3 (high: low) (Table 1). The polyisobutylene is present in a concentration from 50-80% (col. 4, lin. 1-5). The formulation comprises fentanyl (col. 3, lin. 50-5) present in a concentration of 0.01-20 parts by weight of 10 parts (0.01-20%) (col. 3, lin. 55-65). The formulation further includes liquid paraffin and isopropyl myristate (col. 5, lin. 35-60). The compounds are present in an amount approximately 0.5-20 parts by weight based on 100 parts (0.5-20%) (col. 6, lin. 8-16). The pressure sensitive adhesive layer measures 25 square cm and is 200 microns thick (col. 8, lin. 10-20). The concentrations of the reference overlap those of the instant invention, and would obviate the instant claims. The specific concentrations would be arrived art through routine experimentation by those of ordinary skill in the art. Also the reference is silent to the specific molecular weights of the polyisobutylene however high and low molecular weight polymers are well known and similarly weighted polymers are used in combination (col. 4, lin. 18-22). These limitations would be obvious variants and modification well within the level of skill in the art.

With these things in mind it would have been obvious to follow the teachings and suggestions in the rat to modify and perfect the concentrations of the components in order to provide a stable long term transdermal device useful in topical drug delivery. One of ordinary skill in the art would have been motivated to modify the concentrations of the components through routine experimentation since they would provide the optimal results for drug delivery. These modifications would have been obvious and resulted in a stable and safe topical formulation.

Response to Arguments

Applicant's arguments filed 7/02/08 have been fully considered but they are not persuasive. Applicant argues that:

> The Hori patent does not provide sufficient motivation to combine the specific components of the instant claims into a single preparation, and therefore does not obviate the claims.

Regarding this argument it remains the position of the Examiner that the disclosures of the Hori patent continue to obviate the instant claims. The Hori patent discloses a transdermal patch comprising polyisobutylene at a range from 50—60% (claims, abstract). Applicant argues that only the comparative , undesirable examples provide concentration as high as the instant claims. The Examiner disagrees with Applicant assessment. The claims recite that the elastomers present in the invention range in concentration from 50-90% of the dosage from, while the examples, while not binding the inventive disclosures to theory, range specifically from 50 and 70 % of the elastomer with Example 13 containing the polyisobutylene. The broad range encompasses the instantly claimed range while the examples provide ranges close enough in proximity to reduce the modifications to simply optimization of ranges through routine experimentation. Applicant argues that though the ranges may be routine that does not preclude patentability. However Applicant must also provide evidence to an unexpected result due to those ranges. Applicant has provided no such evidence, and as such it can be concluded that there is no unexpected result from modifying the prior art concentrations from 70 parts to 72.5 parts of the instant claims. Regarding the mineral oil concentration and the selection of liquid paraffin, Applicant is reminded that claim 1 does not require liquid paraffin, only broadly claiming mineral oil. Mineral oils are disclosed by the Hori patent as very useful (col. 5, lin. 35-

60) specifically alkanes with 6-24 carbons. These disclosures obviate the broad recitation of a mineral oil present in a particular range. Regarding the selection of fentanyl from the list of possible active agents, Applicant is directed to the Examples where analgesics such as ketoprofen and indomethacin are chosen for transdermal delivery. From this it can be seen that an analgesic patch is the most preferred dosage form (9 out of 14 patches). It would have been obvious to include other more potent analgesic in order to deliver greater pain relief to a patient. Applicant is reminded that the prior art need not teach each and every limitation in a single example in order to obviate. The art need only disclose and suggest the combination of these components and establish that their combination would have been obvious to one of ordinary skill in the art. As such the Hori patent disclose a transdermal patch comprising from 50-90 parts polyisobutylene, up to 20 parts of a mineral oil and an absorption enhancer, along with analgesics selected form a finite list that include fentanyl. For these reasons the claims remain obviated.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618